

THE OFFICE ACTION

In the Office Action issued on February 16, 2006, the Examiner rejected claims 1-6, 9-13 and 17 under 35 U.S.C. §103(a) as being unpatentable over Wakeman. The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Vandeveld. The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Harwardt.

REMARKS

Applicants have carefully considered the Office Action issued on February 16, 2006. Applicants respectfully request reconsideration of the application in light of the following comments. A recent Federal Circuit case analogous to the facts of this case and supporting the Applicants' position (*Perricone v. Medicis Pharm. Corp.*) is discussed below in section B.

A. The Present Claims Are Not Obvious Over Wakeman, Vandeveld or Harwardt

Wakeman is directed to the use of quaternary ammonium aromatic sulfonamides for disinfection and as bacteriostat agents (col. 3, line 13 – col. 4, line 15). Wakeman neither discloses nor suggests a method for the treatment of the specifically claimed diseases by administering compositions containing tosylchloramide(s), tosylchloramide salt(s), and mixtures thereof. In support of his rejection, the Examiner states that it would have been obvious to use the compositions of Wakeman in the treatment of the presently claimed skin diseases because Wakeman discloses the use of tosylchloramide as a topical antiseptic, antidandruff agent, etc. and that one skilled in the art would reasonably have expected that such compositions would be useful in treating the particular skin diseases.

Applicants respectfully traverse. Wakeman neither discloses nor suggests the use of tosylchloramide compounds in the treatment of the particular skin diseases or even diseases that are remotely similar. The causes of the recited skin diseases are many and varied. Is the Examiner suggesting that Wakeman would render claims drawn to the treatment of ANY skin disease using a tosylchloramide composition obvious. The Applicants hope the Examiner will appreciate that this type of argument is completely inappropriate and ill-informed. The fact is that different

ailments require different treatments, and unless such ailments are extremely close in both cause and manifestation (which is not the case here), the use of a compound in the treatment of one would not render obvious its use in the treatment of the other. The useful applications for the reaction products disclosed in Wakeman as mildewproofing, odor preservative, topical antiseptics and disinfection agents, and the like (see column 3, line 39 to column 4, line 15).

The skilled artisan could not expect that a chemical agent useful as disinfectant would be useful as a pharmaceutical for treating diseases of the skin. There are many chemical disinfectants, which do not have appropriate pharmaceutical properties. Furthermore, the skilled artisan could not have received from the overall disclosure of Wakeman any incentive to consider a pharmaceutical activity useful for the treatment of skin diseases using the compounds disclosed therein.

In summary, Wakeman cannot render obvious the subject-matter according to claim 1 of the present invention because the compounds disclosed as microbiologically active compounds are different from tosylchloramide as required in the method according to claim 1 of the present invention. Furthermore, the compounds disclosed in Wakeman are disclosed as microbiologically active disinfectants and there is no hint whatsoever in this document that tosylchloramide could be useful in a method for the treatment of diseases of the skin selected as described in claim 1 of the present invention. Rather, the useful applications for the reaction products disclosed in Wakeman as mildewproofing, odor preservative, topical antiseptics and disinfection agents, and the like (see column 3, line 39 to column 4, line 15).

Vandevelde is directed to an agent which acts against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV), on and/or in inanimate objects, said agent consisting of a chlorinated organic compound which stably and lastingly releases chlorine when in solution, a composition for disinfecting inanimate objects containing at least one of the above-mentioned agents, and the use of such an agent or composition to disinfect inanimate objects, are described, as well as the use of at least one chlorinated organic compound which stably and lastingly released available chlorine when in solution in order to prepare a therapeutic composition which acts against said retrovirus group viruses (see abstract).

Consequently, Vandevelde is explicitly restricted to the use of chlorinated

organic compounds, which stably and lastingly release chlorine, against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV). In contrast, the use against retrovirus diseases is specifically disclaimed in the subject-matter of claim 1 according to the present invention. Despite the Examiner's assertion to the contrary, the fact that the compounds of Vandeveldel are useful against retroviruses does not suggest that they would be useful in the treatment of the skin conditions recited in claim 1. Many, many compounds are used to specifically treat singular conditions. There is simply no suggestion for using the compounds of Vandeveldel in the treatment of the recited diseases. Thus, the subject-matter of claim 1 according to the present invention is not rendered obvious by the disclosure of Vandeveldel.

Further, Vandeveldel is clearly directed to the disinfection of inanimate objects (see abstract and claim 1). The specific teaching of Vandeveldel is the disinfection of inanimate objects against retrovirus group viruses (in particular Human Immunodeficiency Virus [HIV]). Therefore the skilled artisan would not have received any incentives from the disclosure of Vandeveldel to consider the use of tosylchloramide and/or tosylchloramide salts for the manufacture of medicaments to treat diseases of the skin, mucous membranes, organs or tissues, except for treatment of retroviral diseases and disinfection. That is, just because a compound is useful for the disinfection of inanimate objects does not necessarily mean that the compound would be useful could even be used on the skin for treatment of the diseases thereof. Consequently, the subject-matter according to claim 1 of the present invention is also inventive over Vandeveldel.

DE 41 37 544 (Harwardt) is directed to an antimicrobial combination on the basis of compounds, which are able to split off oxygen. The basis of Harwardt is that a special combination of chemical compounds as disinfectant is obtained which is highly active as disinfectant at the same time well tolerated on the skin. Harwardt does by no means disclose a method of treating diseases of the skin. There are many disinfectants which at the same time not useful in methods of treating diseases of the skin and therefore, the skilled artisan when reading the disclosure of Harwardt would not receive any incentive to think along these lines. Therefore, the subject-matter of claim 1 of the present invention is non-obvious over Harwardt.

B. The Examiner's Arguments and Rebuttal Thereof

The main argument of the Examiner seems to be that he deems the use of

certain compounds as disinfectants as rendering obvious the use of such compounds for treating diseases of the skin. However, it is simply not the case that compounds useful as disinfectants are usually also useful for the treatment of skin diseases. To the contrary, disinfectants are normally not useful for the treatment of skin diseases and are in fact not used for such purposes. This is the case for many reasons. One of the reasons is simply that disinfectants are normally not able to penetrate the skin and can therefore not attach microorganisms which are within or under the skin.

The Examiner will appreciate that disinfectants on one hand and compounds for treatment of diseases, including antibiotics and other compounds, are entirely different classes of compounds and have been classified in different classes by the patent office. It is quite rare that compounds useful as disinfectants can successfully be used as pharmaceutical compounds for the treatment of skin diseases.

A recent case decided by the Federal Circuit is illustrative of this position. In *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, (Fed. Cir. 2005). The Court held that claims for a method of treating sunburned skin were not inherently anticipated by prior art directed to cosmetic compositions containing the same exact same compounds for topical application, since the disclosed use of the prior art lotion did not suggest application of the lotion to skin sunburn.

In making this holding, the Court dismissed the district court's holding and the dissent by stating, "Like the district court, the dissent seems to ignore, or at least dismiss as 'not substantial,' the distinction between Dr. Perricone's claimed method and Pereira's disclosed method. Thus, the dissent characterizes both methods the same way: 'Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin.' Unfortunately, the dissent can make that statement only by dismissing the explicit language of Dr. Perricone's claimed method: "applying to the skin sunburn." '693 patent, claim 1. Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn."

In the present case, the prior art is even more dissimilar in that it does not even disclose or suggest topical skin application of the compounds, let alone application to skin for treatment of diseases.

For the reasons indicated above, the subject-matter of the present claims are non-obvious over the cited references.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1-19) are now in condition for allowance. Applicants respectfully request early notification of such allowance. Should any issues remain unresolved, the Examiner is encouraged to contact the undersigned to attempt to resolve any such issues.

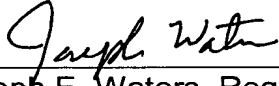
If any fee is due in conjunction with the filing of this response, Applicants authorize deduction of that fee from Deposit Account 06-0308.

Respectfully submitted,

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